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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,470	04/06/2001	Richard W. Layne	1759.17208-FOR	6760
26308	7590	10/19/2004		
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			EXAMINER ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER

3743

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,470

Applicant(s)

LAYNE ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 10 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9 and 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/27/04, 7/28/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated September 2, 2004. Claims 1-21 are pending. Claims 1-4, 7-9 and 11-20 are under consideration and claims 5, 6, 10 and 21 have been withdrawn.

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 7-9, 13, 14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Poddar in US Patent No. 5,102,413.

Regarding claim 1, Poddar discloses a method of directing the expansion of an expandable structure within a bone, via introducing an expandable structure (such as 2) having a longitudinal axis into the bone; introducing a substantially rigid surface (such as 1) into the bone at a location adjacent the expandable structure and along the longitudinal axis of the expandable structure; and expanding the expandable structure within the bone, as recited in columns 3-4 and seen in figures 1-6.

Regarding claim 7, Poddar discloses that as applied to claim 1, as well as, an expandable structure (such as 2) that directly contacts the substantially rigid surface (such as 1) during the expansion step, seen in figures 1-6.

Regarding claim 8, Poddar discloses that as applied to claim 1, as well as, a substantially rigid surface (such as 1) that resists displacement during the expansion step, as recited throughout and seen in figures 1-6.

Regarding claim 9, Poddar discloses that as applied to claim 1, as well as, a substantially rigid surface that is a platform (such as 1). The device can broadly be considered a platform.

Regarding claim 13, Poddar discloses that as applied to claim 1, as well as a substantially rigid surface that is stainless steel, as recited in column 3, lines 25-30.

Regarding claim 14, Poddar discloses that as applied to claim 1, as well as, a substantially rigid surface (such as 1) that extends along substantially the entire length of the expandable structure, as seen in figures 1-6, depending on which direction and orientation the length is considered.

Regarding claim 19, Poddar discloses a device for directing the expansion of an expandable structure (such as 2), having a member extending along a longitudinal axis having a proximal and a distal end and a lumen extending therethrough and a platform (such as 1) extending adjacent the distal end, as recited throughout the specification and figures, depending on which orientation and direction the distal end is considered, as recited in columns 3-5 and seen in figures 1-6.

Regarding claim 20, Poddar discloses that as applied to claim 19, as well as, a platform that is stainless steel, as recited in column 3, lines 25-30.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-4, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poddar in US Patent No. 5,102,413.

Regarding claim 2, Poddar discloses that as applied to claim 1. However, Poddar does not explicitly recite creating a cavity within bone. However, it is within the scope of the invention and would be obvious if not inherent to create or need a cavity.

Regarding claim 3, Poddar discloses that as applied to claim 1. However, Poddar does not explicitly recite an expandable structure that compress at least a portion of a cancellous bone within the bone. On the other hand, compressing cancellous bone is within the scope of the invention although not explicitly recited.

Regarding claim 4, Poddar discloses that as applied to claim 1. However, Poddar does not explicitly recite an expandable structure that displaces at least a portion of a cortical bone within the bone. On the other hand, displacing cortical bone is within the scope of the invention although not explicitly recited.

Regarding claims 15 and 17, Poddar discloses a method of treating a weakened, fractured or diseased bone, via introducing an insertion device; positioning the insertion device such that a platform (such as 1) extending from a distal end of the insertion device is positioned between an expandable device (such as 2) and a portion of the bone region; and expanding the expandable device, as recited throughout the specification and discussed above. However, Poddar does not explicitly recite creating a cavity within the bone and introducing an insertion device through a cortical bone region and into a cancellous bone region of the bone, where that insertion device is positioned between an expandable device and a portion of the cancellous bone region or expandable

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structure is introduced into the cancellous bone region through a lumen in the insertion device. On the other hand, and creating a cavity within the bone is within the scope of the invention and obvious to one with ordinary skill in the art.

6. Claims 11, 12, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poddar in US Patent No. 5,102,413 in view of Mastrorio et al. in US Patent No. 5,849,014.

Regarding claim 11, Poddar discloses that as applied to claim 1, as well as, contracting the expandable structure (16) and removing the structure from the bone. However, Poddar does not recite introducing a filler material into the cavity. On the other hand in column 4, column 5, lines 1-20, and seen in figures 1-4, Mastrorio et al. teaches filler material. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Poddar to include filler as taught by Mastrorio et al. for the purpose of plugging the area.

Regarding claims 12 and 18, Poddar as modified by Mastrorio et al. disclose that as applied to claims 11 and 16. Further, Mastrorio et al. teach filler material that is bone cement, as recited throughout the specification.

Regarding claim 16, Poddar discloses that as applied to claim 15. However, Poddar does not recite filling the cavity with a bone filler. On the other hand in column 4, column 5, lines 1-20, and seen in figures 1-4, Mastrorio et al.

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teaches filler material. Thus, it would be obvious to one with ordinary skill in the art to modify the invention of Poddar to include filler as taught by Mastrorio et al. for the purpose of plugging the area.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

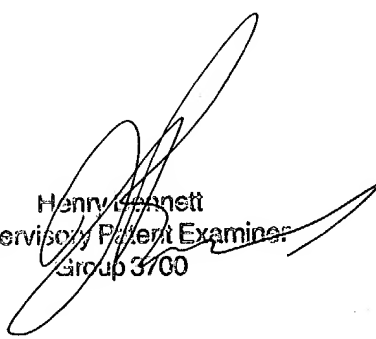
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



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